

K023720

NOV 20 2002

510(K) SUMMARY

Antares Diagnostic Ultrasound System with 4D Basic Imaging

This summary of safety and effectiveness is provided as part of this Premarket Notification in compliance with the Safe Medical Device Act of 1990 revisions to 21 CFR, Part 807.92, Content and Format of a 510(k) Summary.

1. Submitted By:

Siemens Medical Solutions USA, Inc.
22010 S.E. 51st Street
Issaquah, WA 98027-7298

Contact Person:

Judi Hoffman
Regulatory Affairs

Phone: (425) 557-1229

FAX: (425) 391-9198

Date Prepared:

October 14, 2002

2. Proprietary Name:

SONOLINE Antares Ultrasound System

Common/ Usual Name:

Diagnostic Ultrasound System with Accessories

Classification Name:

21 CFR 892.1550

Ultrasonic Pulsed Doppler Imaging System	FR # 892.1550	Product Code 90-IYN
Ultrasonic Pulsed Echo Imaging System	FR # 892.1560	Product Code 90-IYO
Diagnostic Ultrasound Transducer	FR # 892.1570	Product Code 90-ITX

3. Predicate Device:

The Antares system is multi-purpose diagnostic ultrasound system with accessories and proprietary software, and is substantially equivalent to the following products which are already cleared for US distribution with the following 510(k) clearances:

- K001400, 8/1/00, cleared as the Elegra Millennium Advanced, marketed as the Antares
- K003525, 11/22/00, cleared as the Voluson 730 Diagnostic Ultrasound System, marketed as the GE Voluson 730 4D

4. Device Description:

The Antares with 4D Basic Imaging is substantially equivalent to the predicates listed herein. The Antares is a general purpose, mobile, software-controlled, diagnostic ultrasound system with an on-screen display for thermal and mechanical indices related to potential bioeffect mechanisms. Its function is to acquire primary or secondary harmonic ultrasound echo data and display it in B-Mode, M-Mode, Pulsed (PWD) Doppler Mode, Continuous (CWD) Doppler Mode, Color Doppler Mode, Amplitude Doppler Mode, a combination of modes, or Harmonic Imaging, 3D imaging, and 4D Basic Imaging on a CRT display.

The Antares has been designed to meet the following product safety standards:

- UL 2601-1, Safety Requirements for Medical Equipment
- CSA C22.2 No. 601-1, Safety Requirements for Medical Equipment
- AIUM/NEMA UD-3, 1998, Standard for Real Time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment
- AIUM/NEMA UD-2, 1998 Acoustic Output Measurement Standard for Diagnostic Ultrasound
- 93/42/EEC Medical Devices Directive
- Safety and EMC Requirements for Medical Equipment
 - EN 60601-1
 - EN 60601-1-1
 - EN 60601-1-2
- IEC 1157 Declaration of Acoustic Power
- ISO 10993 Biocompatibility

5. Intended Uses:

The Antares ultrasound imaging system is intended for the following applications: General Radiology, Fetal, Abdominal, Intraoperative, Pediatric, Small Parts, Transcranial, OB/GYN, Cardiac, Transesophageal, Pelvic, Neonatal/Adult Cephalic, Urology, Vascular, Musculoskeletal, Superficial Musculoskeletal, and Peripheral Vascular applications.

The system also provides for the measurement of anatomical structures and for analysis packages that provide information that is used for clinical diagnosis purposes.

6. Technological Comparison to Predicate Device:

Antares with 4D Basic Imaging is substantially equivalent to the SONOLINE® Elegra Millennium Enhanced, cleared via K001400, and the Voluson 730 4D Diagnostic Ultrasound System, cleared via K003525. All systems transmit ultrasonic energy into patients, then perform postprocessing of received echoes to generate on-screen display of anatomic structures and fluid flow within the body. All systems allow for specialized measurements of structures and flow, and calculations.

End of 510(k) Summary



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 20 2002

Siemens Medical Solutions USA, Inc.
% Mr. Mark Job
TÜV Product Service, Inc.
1775 Old Highway 8 NW, Suite 104
NEW BRIGHTON MN 55112-1891

Re: K023720

Trade Name: SONOLINE Antares Diagnostic Ultrasound System

Regulation Number: 21 CFR 892.1550

Regulation Name: Ultrasonic pulsed doppler imaging system

Regulation Number: 21 CFR 892.1560

Regulation Name: Ultrasonic pulsed echo imaging system

Regulation Number: 21 CFR 892.1570

Regulation Name: Diagnostic ultrasonic transducer

Regulatory Class: II

Product Code: 90 IYN, IYO, and ITX

Dated: November 4, 2002

Received: November 5, 2002

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the SONOLINE Antares Diagnostic Ultrasound System, as described in your premarket notification:

Transducer Model Number

CW2

CW5

C5-2 Curved Array

CX5-2 Curved Array
VF7-3 Linear Array
EC9-4 Curved Array
VFX9-4 Linear Array
VF10-5 Linear Array
VF13-5 Linear Array
VFX13-5 Multi-D Array
PX4-1 Phased Array
MPT7-4 Multiplane TEE
CH6-2 Curved Array
PH4-1 Phased Array
P10-4 Phased Array
VF13-5SP Linear Array
C5F1 Curved Array
C7F2 Curved Array Mechanical 3D

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This determination of substantial equivalence is granted on the condition that prior to shipping the first device, you submit a postclearance special report. This report should contain complete information, including acoustic output measurements based on production line devices, requested in Appendix G, (enclosed) of the Center's September 30, 1997 "Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers." If the special report is incomplete or contains unacceptable values (e.g., acoustic output greater than approved levels), then the 510(k) clearance may not apply to the production units which as a result may be considered adulterated or misbranded.

The special report should reference the manufacturer's 510(k) number. It should be clearly and prominently marked "ADD-TO-FILE" and should be submitted in duplicate to:

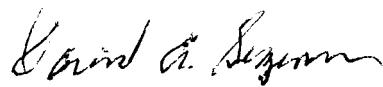
Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, Maryland 20850

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801, please contact the Office of Compliance at (301) 594-4591. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597 or at its Internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

If you have any questions regarding the content of this letter, please contact Rodrigo C. Perez at (301) 594-1212.

Sincerely yours,



for Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure(s)

FDA Cleared Indications for Use Forms

510 (k) Number (if known): K001400

Device Name:
Intended Use:

SONOLINE Antares

Ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal	P	P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8
Abdominal	P	P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8
Intraoperative (Note 9)	N	N	N	P	N	N	N		BMDC	Note 2,3,4,5,7,8
Intraoperative Neurological	N	N	N		N	N	N		BMDC	Note 2,3,4,5,7,8
Pediatric	P	P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8
Small Organ (Note 1)	P	P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8
Neonatal Cephalic	P	P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8
Adult Cephalic	P	P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8
Cardiac	P	P	P	P	P	P	P		BMDC	Note 2,3,4,5,6,7,8
Trans-esophageal	P	P	P	P	P	P	P		BMDC	Note 2,3,4,5,6
Transrectal	P	P	P		P	P	P		BMDC	Note 2,3,4,5,7,8
Transvaginal	P	P	P		P	P	P		BMDC	Note 2,3,4,5,7,8
Transurethral										
Intravascular										
Peripheral vessel	P	P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8
Laparoscopic										
Musculo-skeletal Conventional	P	P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8
Musculo-skeletal Superficial	P	P	P		P	P	P		BMDC	Note 2,3,4,5,7,8
Other (specify)										

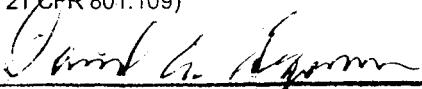
N = new indication; P = previously cleared by FDA; E = added under Appendix E

Additional Comments:

Note 1 For example: breast, testes, thyroid, penis, prostate, etc.
 Note 2 Ensemble tissue harmonic imaging
 Note 3 SieClear multi-view spatial compounding
 Note 4 Tissue Equalization Technology
 Note 5 3-Scape real-time 3D imaging
 Note 6 Cadence contrast agent imaging
 Note 7 B&W SieScape panoramic imaging
 Note 8 Power SieScape panoramic imaging
 Note 9 For example: vascular, abdominal

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices

Diagnostic Ultrasound Indications for Use Form

510 (k) Number (if known): K001400

Device Name: CW2 Probe for use with SONOLINE Antares

Intended Use: Ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal					P					
Abdominal					P					
Intraoperative (Note 9)					P					
Intraoperative Neurological										
Pediatric					P					
Small Organ (Note 1)					P					
Neonatal Cephalic					P					
Adult Cephalic					P					
Cardiac					P					
Trans-esophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral vessel					P					
Laparoscopic										
Musculo-skeletal Conventional					P					
Musculo-skeletal Superficial										
Other (specify)										

N = new indication; P = previously cleared by FDA; E = added under Appendix E

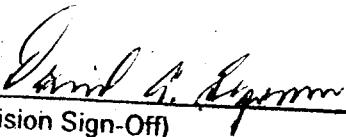
Additional Comments:

Note 1 For example: breast, testes, thyroid, penis, prostate, etc.

Note 9 For example: vascular, abdominal

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)


 (Division Sign-Off)
 Division of Reproductive, Abdominal,
 and Radiological Devices
 510(k) Number K023730

Diagnostic Ultrasound Indications for Use Form

510 (k) Number (if known):

Device Name: CW5 Probe for use with SONOLINE Antares

Intended Use: Ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal					N					
Abdominal					N					
Intraoperative (Note 9)					N					
Intraoperative Neurological										
Pediatric					N					
Small Organ (Note 1)					N					
Neonatal Cephalic					N					
Adult Cephalic					N					
Cardiac					N					
Trans-esophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral vessel					N					
Laparoscopic										
Musculo-skeletal Conventional					N					
Musculo-skeletal Superficial										
Other (specify)										

N = new indication; P = previously cleared by FDA; E = added under Appendix E

Additional Comments:

Note 1 For example: breast, testes, thyroid, penis, prostate, etc.

Note 9 For example: vascular, abdominal

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

David A. Ferguson
 (Division Sign-Off)
 Division of Reproductive, Abdominal
 & Endocrinological Devices

KLA 3730

Diagnostic Ultrasound Indications for Use Form

510 (k) Number (if known): **K001400**Device Name: **C5-2 Curved Array Transducer for use with SONOLINE Antares**
Intended Use: **Ultrasound imaging or fluid flow analysis of the human body as follows:**

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8
Abdominal		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8
Intraoperative Abdominal										
Intraoperative Neurological										
Pediatric		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8
Small Organ										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Trans-esophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral vessel		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8
Laparoscopic										
Musculo-skeletal Conventional		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8
Musculo-skeletal Superficial										
Other (specify)										

N = new indication; P = previously cleared by FDA; E = added under Appendix E

Additional Comments:

- Note 2 Ensemble tissue harmonic imaging
- Note 3 SieClear multi-view spatial compounding
- Note 4 Tissue Equalization Technology
- Note 5 3-Scape real-time 3D imaging
- Note 7 B&W SieScape panoramic imaging
- Note 8 Power SieScape panoramic imaging

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

David A. Segev
 (Division Sign-Off)
 Division of Reproductive, Abdominal,
 and Radiological Devices
 510(k) Number K001400

Diagnostic Ultrasound Indications for Use Form

510 (k) Number (if known): K001400

Device Name: CX5-2 Curved Array Transducer for use with SONOLINE Antares
Intended Use: Ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8
Abdominal		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8
Intraoperative Abdominal										
Intraoperative Neurological										
Pediatric		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8
Small Organ										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Trans-esophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral vessel		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8
Laparoscopic										
Musculo-skeletal Conventional		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8
Musculo-skeletal Superficial										
Other (specify)										

N = new indication; P = previously cleared by FDA; E = added under Appendix E

Additional Comments:

- Note 2 Ensemble tissue harmonic imaging
- Note 3 SieClear multi-view spatial compounding
- Note 4 Tissue Equalization Technology
- Note 5 3-Scape real-time 3D imaging
- Note 7 B&W SieScape panoramic imaging
- Note 8 Power SieScape panoramic imaging

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

David A. Lefman
 (Division Sign-Off)
 Division of Reproductive, Abdominal,
 and Radiological Devices
 510(k) Number *K0237*

Diagnostic Ultrasound Indications for Use Form

510 (k) Number (if known): K001400

Device Name: VF7-3 Linear Array Transducer for use with SONOLINE Antares

Intended Use: Ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8
Abdominal		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8
Intraoperative Abdominal										
Intraoperative Neurological										
Pediatric		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8
Small Organ (Note 1)		E	E	E		E	E		BMDC	Note 2,3,4,5,7,8
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Trans-esophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral vessel		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8
Laparoscopic										
Musculo-skeletal Conventional		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8
Musculo-skeletal Superficial		E	E	E		E	E		BMDC	Note 2,3,4,5,7,8
Other (specify)										

N = new indication; P = previously cleared by FDA; E = added under Appendix E

Additional Comments:

Note 1 For example: breast, testes, thyroid, penis, prostate, etc.

Note 2 Ensemble tissue harmonic imaging

Note 3 SieClear multi-view spatial compounding

Note 4 Tissue Equalization Technology

Note 5 3-Scape real-time 3D imaging

Note 7 B&W SieScape panoramic imaging

Note 8 Power SieScape panoramic imaging

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

David A. Johnson
 (Division Sign-Off)
 Division of Reproductive, Abdominal,
 and Radiological Devices
 510(k) Number K023720

Diagnostic Ultrasound Indications for Use Form

510 (k) Number (if known): K001400

Device Name: EC9-4 Curved Array Transducer for use with SONOLINE Antares
Intended Use: Ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal		E	E	E		E	E		BMDC	Note 2,3,4,5,7,8
Abdominal										
Intraoperative Abdominal										
Intraoperative Neurological										
Pediatric										
Small Organ (Note 1)		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8
Neonatal Cephalic		E	E	E		E	E		BMDC	Note 2,3,4,5,7,8
Adult Cephalic										
Cardiac										
Trans-esophageal										
Transrectal		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8
Transvaginal		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8
Transurethral										
Intravascular										
Peripheral vessel										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)										

N = new indication; P = previously cleared by FDA; E = added under Appendix E

Additional Comments:

Note 1 For example: breast, testes, thyroid, penis, prostate, etc.
 Note 2 Ensemble tissue harmonic imaging
 Note 3 SieClear multi-view spatial compounding
 Note 4 Tissue Equalization Technology
 Note 5 3-Scape real-time 3D imaging
 Note 7 B&W SieScape panoramic imaging
 Note 8 Power SieScape panoramic imaging

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)

Division of Reproductive, Abdominal,
and Radiological Devices

510(k) Number

K001400

Diagnostic Ultrasound Indications for Use Form

510 (k) Number (if known): K001400

Device Name: VFX9-4 Linear Array Transducer for use with SONOLINE Antares
Intended Use: Ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8
Abdominal		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8
Intraoperative Abdominal										
Intraoperative Neurological										
Pediatric		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8
Small Organ (Note 1)		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8
Neonatal Cephalic		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8
Adult Cephalic										
Cardiac										
Trans-esophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral vessel		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8
Laparoscopic										
Musculo-skeletal Conventional		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8
Musculo-skeletal Superficial		E	E	E		E	E		BMDC	Note 2,3,4,5,7,8
Other (specify)										

N = new indication; P = previously cleared by FDA; E = added under Appendix E

Additional Comments:

Note 1 For example: breast, testes, thyroid, penis, prostate, etc.

Note 2 Ensemble tissue harmonic imaging

Note 3 SieClear multi-view spatial compounding

Note 4 Tissue Equalization Technology

Note 5 3-Scape real-time 3D imaging

Note 7 B&W SieScape panoramic imaging

Note 8 Power SieScape panoramic imaging

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)


 Division Sign-Off

Division of Reproductive, Abdominal,

and Endocrinological Devices

KCB/120

Diagnostic Ultrasound Indications for Use Form

510 (k) Number (if known): K001400

Device Name: VF10-5 Linear Array Transducer for use with SONOLINE Antares

Intended Use: Ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8
Abdominal		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8
Intraoperative Abdominal										
Intraoperative Neurological										
Pediatric		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8
Small Organ (Note 1)		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8
Neonatal Cephalic		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8
Adult Cephalic										
Cardiac										
Trans-esophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral vessel		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8
Laparoscopic										
Musculo-skeletal Conventional		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8
Musculo-skeletal Superficial		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8
Other (specify)										

N = new indication; P = previously cleared by FDA; E = added under Appendix E

Additional Comments:

Note 1 For example: breast, testes, thyroid, penis, prostate, etc.
 Note 2 Ensemble tissue harmonic imaging
 Note 3 SieClear multi-view spatial compounding
 Note 4 Tissue Equalization Technology
 Note 5 3-Scape real-time 3D imaging
 Note 6 B&W SieScape panoramic imaging
 Note 7 Power SieScape panoramic imaging

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 Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)

Division of Reproductive, Abdominal,
and Radiological Devices

510(k) Number

K043120

Diagnostic Ultrasound Indications for Use Form

510 (k) Number (if known): **K001400**Device Name: **VF13-5 Linear Array Transducer for use with SONOLINE Antares**

Intended Use: Ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal		E	E	E		E	E		BMDC	Note 2,3,4,5,7,8
Abdominal	E	E	E			E	E		BMDC	Note 2,3,4,5,7,8
Intraoperative Abdominal										
Intraoperative Neurological										
Pediatric	P	P	P			P	P		BMDC	Note 2,3,4,5,7,8
Small Organ (Note 1)	P	P	P			P	P		BMDC	Note 2,3,4,5,7,8
Neonatal Cephalic	E	E	E			E	E		BMDC	Note 2,3,4,5,7,8
Adult Cephalic										
Cardiac										
Trans-esophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral vessel	P	P	P			P	P		BMDC	Note 2,3,4,5,7,8
Laparoscopic	P	P	P			P	P		BMDC	Note 2,3,4,5,7,8
Musculo-skeletal Conventional	P	P	P			P	P		BMDC	Note 2,3,4,5,7,8
Musculo-skeletal Superficial	P	P	P			P	P		BMDC	Note 2,3,4,5,7,8
Other (specify)										

N = new indication; P = previously cleared by FDA; E = added under Appendix E

Additional Comments:

Note 1 For example: breast, testes, thyroid, penis, prostate, etc.

Note 2 Ensemble tissue harmonic imaging

Note 3 SieClear multi-view spatial compounding

Note 4 Tissue Equalization Technology

Note 5 3-Scape real-time 3D imaging

Note 7 B&W SieScape panoramic imaging

Note 8 Power SieScape panoramic imaging

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

David A. Leyman
 (Division Sign-Off)
 Division of Reproductive, Abdominal,
 and Radiological Devices
 510(k) Number *1023720*

Diagnostic Ultrasound Indications for Use Form

510 (k) Number (if known): K001400

Device Name: VFX13-5 Multi-D Array Transducer for use with SONOLINE Antares
Intended Use: Ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal		E	E	E		E	E		BMDC	Note 2,3,4,5,7,8
Abdominal		E	E	E		E	E		BMDC	Note 2,3,4,5,7,8
Intraoperative Abdominal										
Intraoperative Neurological										
Pediatric		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8
Small Organ (Note 1)		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8
Neonatal Cephalic		E	E	E		E	E		BMDC	Note 2,3,4,5,7,8
Adult Cephalic										
Cardiac										
Trans-esophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral vessel		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8
Laparoscopic										
Musculo-skeletal Conventional		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8
Musculo-skeletal Superficial		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8
Other (specify)										

N = new indication; P = previously cleared by FDA; E = added under Appendix E

Additional Comments:

Note 1 For example: breast, testes, thyroid, penis, prostate, etc.
 Note 2 Ensemble tissue harmonic imaging
 Note 3 SieClear multi-view spatial compounding
 Note 4 Tissue Equalization Technology
 Note 5 3-Scape real-time 3D imaging
 Note 7 B&W SieScape panoramic imaging
 Note 8 Power SieScape panoramic imaging

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

David A. Segmon
(Division Sign-Off)Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K093170

Diagnostic Ultrasound Indications for Use Form

510 (k) Number (if known): **K001400 (formerly cleared as PX5-2)**Device Name: **PX4-1 Phased Array Transducer for use with SONOLINE Antares**
Intended Use: **Ultrasound imaging or fluid flow analysis of the human body as follows:**

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal	P	P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8
Abdominal	P	P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8
Intraoperative Abdominal										
Intraoperative Neurological										
Pediatric	P	P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8
Small Organ										
Neonatal Cephalic	P	P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8
Adult Cephalic	P	P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8
Cardiac	P	P	P	P	P	P	P		BMDC	Note 2,3,4,5,6,7,8
Trans-esophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral vessel	P	P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)										

N = new indication; P = previously cleared by FDA; E = added under Appendix E

Additional Comments:

- Note 2 Ensemble tissue harmonic imaging
- Note 3 SieClear multi-view spatial compounding
- Note 4 Tissue Equalization Technology
- Note 5 3-Scape real-time 3D imaging
- Note 6 Cadence contrast agent imaging
- Note 7 B&W SieScape panoramic imaging
- Note 8 Power SieScape panoramic imaging

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)

Division of Reproductive, Abdominal

and Radiological Devices

510(k) Number

K023190

Diagnostic Ultrasound Indications for Use Form

510 (k) Number (if known): K001400 (formerly cleared as M7-4)
K020353 Omnia X/XSDevice Name: MPT7-4 Multiplane TEE Transducer for use with SONOLINE Antares
Intended Use: Ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative Abdominal										
Intraoperative Neurological										
Pediatric										
Small Organ										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Trans-esophageal	P	P	P	P	P	P		BMDC	Note 2,3,4,5,6	
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral vessel										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)										

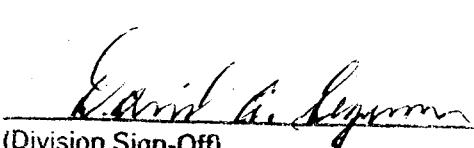
N = new indication; P = previously cleared by FDA; E = added under Appendix E

Additional Comments:

Note 2 Ensemble tissue harmonic imaging
 Note 3 SieClear multi-view spatial compounding
 Note 4 Tissue Equalization Technology
 Note 5 3-Scape real-time 3D imaging
 Note 6 Cadence contrast agent imaging

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 Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)


(Division Sign-Off)Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K023730

Diagnostic Ultrasound Indications for Use Form

510 (k) Number (if known): K001400 (formerly cleared as C7-3)

Device Name: CH6-2 Curved Array Transducer for use with SONOLINE Antares
Intended Use: Ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal	P	P	P			P	P		BMDC	Note 2,3,4,5,7,8
Abdominal	P	P	P			P	P		BMDC	Note 2,3,4,5,7,8
Intraoperative Abdominal										
Intraoperative Neurological										
Pediatric	P	P	P			P	P		BMDC	Note 2,3,4,5,7,8
Small Organ										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Trans-esophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral vessel	P	P	P			P	P		BMDC	Note 2,3,4,5,7,8
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)										

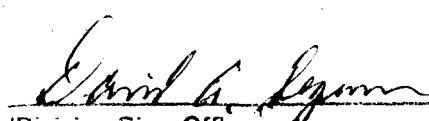
N = new indication; P = previously cleared by FDA; E = added under Appendix E

Additional Comments:

Note 2 Ensemble tissue harmonic imaging
 Note 3 SieClear multi-view spatial compounding
 Note 4 Tissue Equalization Technology
 Note 5 3-Scape real-time 3D imaging
 Note 7 B&W SieScape panoramic imaging
 Note 8 Power SieScape panoramic imaging

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Prescription Use (Per 21 CFR 801.109)



(Division Sign-Off)

Division of Reproductive, Abdominal

and Radiological Devices

510(k) Number

K001400

Diagnostic Ultrasound Indications for Use Form

510 (k) Number (if known): **K001400 (formerly cleared as P3-2)**Device Name: **PH4-1 Phased Array Transducer for use with SONOLINE Antares**
Intended Use: Ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8
Abdominal		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8
Intraoperative Abdominal										
Intraoperative Neurological										
Pediatric		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8
Small Organ										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Trans-esophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral vessel		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)										

N = new indication; P = previously cleared by FDA; E = added under Appendix E

Additional Comments:

- Note 2 Ensemble tissue harmonic imaging
- Note 3 SieClear multi view spatial compounding
- Note 4 Tissue Equalization Technology
- Note 5 3-Scape real-time 3D imaging
- Note 7 B&W SieScape panoramic imaging
- Note 8 Power SieScape panoramic imaging

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)

Division of Reproductive, Abdominal,
and Radiological Devices
NDA Number

K023140

Diagnostic Ultrasound Indications for Use Form

510 (k) Number (if known): K001400 (formerly cleared as P9-4)

Device Name: P10-4 Phased Array Transducer for use with SONOLINE Antares
Intended Use: Ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal										
Abdominal	P	P	P	P	P	P			BMDC	Note 2,3,4,5,7,8
Intraoperative Abdominal										
Intraoperative Neurological										
Pediatric	P	P	P	P	P	P			BMDC	Note 2,3,4,5,7,8
Small Organ										
Neonatal Cephalic	P	P	P	P	P	P			BMDC	Note 2,3,4,5,7,8
Adult Cephalic										
Cardiac	P	P	P	P	P	P			BMDC	Note 2,3,4,5,6,7,8
Trans-esophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral vessel	P	P	P	P	P	P			BMDC	Note 2,3,4,5,7,8
Laparoscopic										
Musculo-skeletal Conventional	P	P	P	P	P	P			BMDC	Note 2,3,4,5,7,8
Musculo-skeletal Superficial										
Other (specify)										

N = new indication; P = previously cleared by FDA; E = added under Appendix E

Additional Comments:

- Note 2 Ensemble tissue harmonic imaging
- Note 3 SieClear multi view spatial compounding
- Note 4 Tissue Equalization Technology
- Note 5 3-Scape real-time 3D imaging
- Note 6 Cadence contrast agent imaging
- Note 7 B&W SieScape panoramic imaging
- Note 8 Power SieScape panoramic imaging

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Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)

Division of Reproductive, Abdominal,
and Radiological Devices

510(k) Number

1023120

Diagnostic Ultrasound Indications for Use Form

510 (k) Number (if known):

Device Name: VF13-5SP Linear Array Transducer for use with SONOLINE Antares

Indications For Use: Diagnostic imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (Note 9)	N	N	N			N	N		BMDC	Note 2,3,4,5,7,8
Intraoperative Neurological	N	N	N			N	N		BMDC	Note 2,3,4,5,7,8
Pediatric	N	N	N			N	N		BMDC	Note 2,3,4,5,7,8
Small Organ (Note 1)	N	N	N			N	N		BMDC	Note 2,3,4,5,7,8
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral vessel	N	N	N			N	N		BMDC	Note 2,3,4,5,7,8
Laparoscopic										
Musculo-skeletal Conventional	N	N	N			N	N		BMDC	Note 2,3,4,5,7,8
Musculo-skeletal Superficial	N	N	N			N	N		BMDC	Note 2,3,4,5,7,8
Other (specify)										

N = new indication; P = previously cleared by FDA; E = added under Appendix E

Additional Comments:

Note 1 For example: breast, testes, thyroid, penis, prostate, etc.

Note 2 Ensemble tissue harmonic imaging

Note 3 SieClear multi-view spatial compounding

Note 4 Tissue Equalization Technology

Note 5 3-Scape real-time 3D imaging

Note 7 B&W SieScape panoramic imaging

Note 8 Power SieScape panoramic imaging

Note 9 For example: vascular, abdominal

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

David A. Lyon
 (Division Sign-Off)
 Division of Reproductive, Abdominal,
 and Radiological Devices
 510(k) Number *K033140*

Diagnostic Ultrasound Indications for Use Form

510 (k) Number (if known):

Device Name: **C5F1 Curved array mechanical 3D transducer for use with SONOLINE Antares**
Intended Use: Ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal		N	N	N		N	N		BMDC	Note 2,3,4,5,7,8
Abdominal	N	N	N			N	N		BMDC	Note 2,3,4,5,7,8
Intraoperative Abdominal										
Intraoperative Neurological										
Pediatric	N	N	N			N	N		BMDC	Note 2,3,4,5,7,8
Small Organ										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Trans-esophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral vessel	N	N	N			N	N		BMDC	Note 2,3,4,5,7,8
Laparoscopic										
Musculo-skeletal Conventional	N	N	N			N	N		BMDC	Note 2,3,4,5,7,8
Musculo-skeletal Superficial										
Other (specify)										

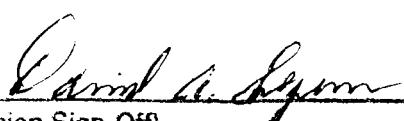
N = new indication; P = previously cleared by FDA; E = added under Appendix E

Additional Comments:

- Note 2 Ensemble tissue harmonic imaging
- Note 3 SieClear multi-view spatial compounding
- Note 4 Tissue Equalization Technology
- Note 5 3-Scape real-time 3D imaging
- Note 7 B&W SieScape panoramic imaging
- Note 8 Power SieScape panoramic imaging

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)


 (Division Sign-Off)
 Division of Reproductive, Abdominal,
 and Radiological Devices
 510(k) Number DD3120

Diagnostic Ultrasound Indications for Use Form

510 (k) Number (if known):

Device Name: **C7F2 Curved array mechanical 3D transducer for use with SONOLINE Antares**
Intended Use: **Ultrasound imaging or fluid flow analysis of the human body as follows:**

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal		N	N	N		N	N		BMDC	Note 2,3,4,5,7,8
Abdominal		N	N	N		N	N		BMDC	Note 2,3,4,5,7,8
Intraoperative Abdominal										
Intraoperative Neurological										
Pediatric		N	N	N		N	N		BMDC	Note 2,3,4,5,7,8
Small Organ										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Trans-esophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral vessel		N	N	N		N	N		BMDC	Note 2,3,4,5,7,8
Laparoscopic										
Musculo-skeletal Conventional		N	N	N		N	N		BMDC	Note 2,3,4,5,7,8
Musculo-skeletal Superficial										
Other (specify)										

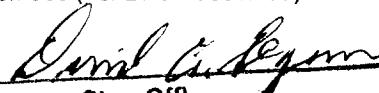
N = new indication; P = previously cleared by FDA; E = added under Appendix E

Additional Comments:

Note 2 Ensemble tissue harmonic imaging
 Note 3 SieClear multi-view spatial compounding
 Note 4 Tissue Equalization Technology
 Note 5 3-Scape real-time 3D imaging
 Note 7 B&W SieScape panoramic imaging
 Note 8 Power SieScape panoramic imaging

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 Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)


 (Division Sign-Off)
 Division of Reproductive, Abdominal,
 and Radiological Devices
 510(k) Number K033120